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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,070	06/25/2003	Samuel M. Shaolian	14307-6	6535

21967 7590 12/19/2006
HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER

HOFFMAN, MARY C

ART UNIT PAPER NUMBER

3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/607,070	Applicant(s) SHAOLIAN ET AL.	
	Examiner Mary Hoffman	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-15, 17-29 and 31-33 is/are rejected.
- 7) ☒ Claim(s) 12, 16 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 13-15, 17-25 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al. (U.S. Patent No. 6,740,090) in view of Carl (U.S. Patent No. 6,613,044).

Cragg et al. disclose a method for treating diseases and conditions that change the spatial relationship between a first vertebral body of a first vertebra, a second vertebral body of a second vertebra adjacent the first vertebra, and a first intervertebral disk between the first vertebral body and the second vertebral body, or that cause instability of the vertebral column, or both and a method that allows the surgeon to access the first intervertebral disk to restore a more normal three-dimensional configuration of the first intervertebral disk between the first vertebral body and the second vertebral body, the method comprising selecting a patient, creating a channel to the first vertebra; and removing at least part of the first intervertebral disk through the channel. The patient has pain caused by the change in spatial relationship of the vertebra, with a disease such as scoliosis (col. 1, lines 35-37, col. 2, lines 35-45). The access channels are bilateral (FIG. 27 and 28). The access is created using a non-

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flexible drill (col. 8, lines 23-35, see methods for forming a pilot hole in application 09/640222, incorporated by reference). The access is created using a needle (col. 8, lines 23-35, see methods for forming a pilot hole in application 09/640222, incorporated by reference, page 13, paragraph 2). A sheath, or retainer tube, is inserted into the channel (col. 17, lines 65-67). The method comprises actuating a first flexible drill and extending it through the channel (col. 11). The first flexible drill comprises a drilling tip, capable of orienting the drilling tip at a predetermined position after accessing a material to be drilled through a substantially straight passage having a long axis, wherein the predetermine portion is at least 10 degrees off the long axis of the substantially straight passage. The first flexible drill comprises a guiding tube (ref. #226) with a proximal segment having a central axis and a distal segment giving a distal end, and the drilling tip is connected to the distal end. The guiding tube is made of a substance that allows it to return to a shape when not subject to distortion. The drilling tip has a radius of curvature between 10 degrees and 150 degrees off the central axis of the proximal segment. A second flexible drill is actuated and enlarges the channel (col. 17, lines 52-64). The second flexible drill comprises a drilling tip, capable of orienting the drilling tip at a predetermined position after accessing a material to be drilled through a substantially straight passage having a long axis, wherein the predetermined portion is at least 10 degrees off the long axis of the substantially straight passage. The second flexible drill comprises a guiding tube with a proximal segment having a central axis and a distal segment giving a distal end, and the drilling tip is connected to the distal end. The guiding tube is made of a substance that allows it to return to a shape when not

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subject to distortion. The drilling tip has a radius of curvature between 10 degrees and 150 degrees off the central axis of the proximal segment. A guide wire is used, using an over-the-wire technique (col. 12, lines 1-17). The cutting device comprises a pivoting blade connected at a distal end of a flexible shaft, a locking sleeve surrounding at least part of the flexible shaft, the blade pivoting from a first insertion position to a second cutting position, where the blade has one notch, where the locking sleeve can be advanced distally and retracted proximally, where advancement distally causes the locking sleeve to engage with one notch, thereby locking the blade into the cutting position and retraction proximally causes the locking sleeve to disengage from the one notch thereby unlocking the blade from the cutting position (FIG. 22 and 25) The method comprises an enucleation device (FIG. 37-40) that comprises a proximal end, distal end comprising a cutting cap with a plurality of deformable blades, a shaft between the proximal end and the cutting cap, where the plurality of deformable blades can cut material in a space when the blades are not deformed, and after accessing the space through a passage while the blades are deformed, and the passage has a smaller cross-section than the material cross-section of the un-deformed blades while the blades are cutting the material (col. 20, lines 32-36). The method includes cutting the intervertebral disk and the endplate (see FIG. 18). A fusion agent containment device with fusion agent is inserted into the disk space, and the first vertebra is fused to the second and third (col. 3, lines 55-end, and col. 22, lines 62-64). The method includes a distraction system to distract the first vertebral body from the second (col. 22, lines 62-64).

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Cragg et al. disclose the claimed invention except for the obtaining transpedicular access to the first intervertebral disk.

Carl discloses obtaining transpedicular access to the first intervertebral disk as one of the variety of surgical approaches practiced by surgeons to provide access to intervertebral discs and is less invasive to abdominal organs than an anterior surgical approach (col. 5, lines 4-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Cragg et al. to obtain transpedicular access to the first intervertebral disk in view of Carl because it is one of the variety of surgical approaches practiced by surgeons to provide access to intervertebral discs and it is less invasive to abdominal organs than an anterior surgical approach

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al. (U.S. Patent No. 6,740,090) in view of Carl (U.S. Patent No. 6,613,044) further in view of Kuslich (U.S. Patent No. 6,712,853).

Cragg et al. in view of Carl disclose the claimed invention except for inserting a fusion agent containment device and partially filling it with fusion agent, the fusion agent containment device comprising a band of thin, biocompatible, deformable material having shape memory and configured to expand into a circular shape when undeformed.

Kuslich discloses a fusion agent containment device inserted into the vertebral disc (col. 9, lines 7-8) and partially filling it with fusion agent (col. 10, lines 25-30), the fusion agent containment device comprising a band of thin, biocompatible, deformable

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material having shape memory and configured to expand into a circular shape when undeformed in order to stabilize a disc.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Cragg et al. in view of Carl including inserting a fusion agent containment device into the vertebral disc and partially filling it with fusion agent, the fusion agent containment device comprising a band of thin, biocompatible, deformable material having shape memory and configured to expand into a circular shape when undeformed in view of Kuslich in order to stabilize a disc.

Claims 28 and 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg et al. (U.S. Patent No. 6,740,090) in view of Carl (U.S. Patent No. 6,613,044) further in view of Vaccaro (U.S. Patent No. 6,102,950).

Cragg et al. in view of Carl disclose the claimed invention except for the distraction system comprising an introducer comprising a proximal insertion portion and a distal anchoring portion, a plurality of deformable, spacing components, each spacing component having a central opening and a plurality of extensions, and each spacing component is configured to stack onto the insertion portion of the introducer. Cragg et al. in view of Carl also do not disclose the distraction system comprising a proximal connecting portion, a distal distracting portion comprising a plurality of strips, where each strip is deformable from an extended configuration to a curled configuration, each strip having a distal and proximal end, where the proximal ends are joined to the proximal connecting portion.

Vaccaro discloses an introducer comprising a proximal insertion portion (ref. #32) and a distal anchoring portion (rest of ref. #20 located distal to ref. #32), a plurality of deformable, spacing components (ref. #80 and 40), each spacing component having a central opening (ref. #36 and 88) and a plurality of extensions (ref. #82 and 44), and each spacing component is configured to stack onto the insertion portion of the introducer, as well as the distraction system comprising a proximal connecting portion(ref. #60), a distal distracting portion comprising a plurality of strips (ref. #50), where each strip is deformable from an extended configuration to a curled configuration, each strip having a distal and proximal end, where the proximal ends are joined to the proximal connecting portion, in order to provide a intervertebral body fusion device that provides the proper angle of lordosis between the vertebrae (col. 4, lines 40-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Cragg et al. in view of Carl and using a distraction system comprising an introducer comprising a proximal insertion portion and a distal anchoring portion, a plurality of deformable, spacing components, each spacing component having a central opening and a plurality of extensions, and each spacing component is configured to stack onto the insertion portion of the introducer, a proximal connecting portion, a distal distracting portion comprising a plurality of strips, where each strip is deformable from an extended configuration to a curled configuration, each strip having a distal and proximal end, where the proximal ends are joined to the proximal connecting portion in view of Vaccaro in order to provide a intervertebral body fusion device that provides the proper angle of lordosis between the vertebrae.

Allowable Subject Matter

Claims 12, 16, and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 09/27/2006 have been fully considered but they are not persuasive. Applicant argues that the examiner has failed to establish a prima facie case of obviousness in the rejection of Cragg et al. in view of Carl because 1.) the examiner has not provided a sufficient motivation to combine the two references, and 2.) that the Carl reference does not disclose obtaining transpedicular access to the first intervertebral disk by creating a channel through a pedicle of the first vertebra.

In response to Applicant's contention that the examiner did not provide sufficient motivation, the examiner respectfully disagrees. The Cragg et al. reference discloses the claimed invention except for the surgical approach, i.e. accessing the spine via transpedicular access. The Cragg et al. reference discloses creating a channel to the vertebral bodies via anterior approaches (Fig. 14) and posterior approaches (Fig. 20), but not a transpedicular approach, i.e. an approach through a pedicle. The Carl disclosure shows that there are a variety of well known surgical approaches than can be used in procedures that relate to the spine, including access through the pedicle, or transpedicular access (col. 5, lines 4-25). The Carl reference mentions that one

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particular approach is an anterior approach (which is one of the approaches also used in the Cragg et al. reference), however, the anterior approach is invasive to the abdominal organs. The Carl reference then goes further to cite alternatives to an anterior approach that would be less invasive, i.e. not affect the abdominal organs, such as a transpedicular approach.

In response to Application's contention that the Carl reference does not disclose obtaining transpedicular access to the first intervertebral disk by creating a channel through a pedicle of the first vertebra, it is noted that the Cragg et al. reference drills to create a channel in the bone, and then combining the Cragg et al. reference with the Carl reference, which discloses that surgical procedures can be performed using the transpedicular approach, i.e. through a pedicle, would provided the limitation of obtaining transpedicular access to the first intervertebral disk by creating a channel through a pedicle of the first vertebra. Therefore, the examiner does not understand Applicant's argument that states that the combination of Cragg et al. and Carl does not disclose all the claimed features.

Therefore, the examiner maintains that the 103(a) rejections under Cragg et al. in view of Carl and, further in view of Kuslich and Vaccaro, are proper, since the motivation, being that a transpedicular approach is less invasive than an anterior approach, is deemed a sufficient motivation, and the combination of the Cragg et al. and Carl references discloses all of the claimed limitations.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER